

# इंटरनेट

# मानक

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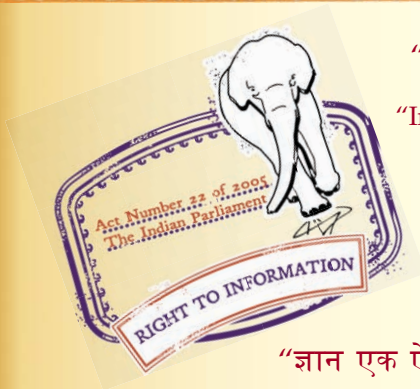
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IS 9165-1 (1992): Surgical instruments - Needles, suture,  
Part 1: Specification [MHD 1: Surgical Instruments]



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Bhartrhari—Nitiśatakam

“Knowledge is such a treasure which cannot be stolen”



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भारतीय मानक

शल्यक उपकरण — सीवन सुइयाँ

भाग 1 विशिष्ट

( पहला पुनरीक्षण )

*Indian Standard*

**SURGICAL INSTRUMENTS — NEEDLES,  
SUTURE**

**PART 1 SPECIFICATION**

*( First Revision )*

UDC 615.472.2 : 616-089.84-7

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**BUREAU OF INDIAN STANDARDS**  
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## FOREWORD

This Indian Standard ( Part 1 ) ( First Revision ) was adopted by the Bureau of Indian Standards, after the draft finalized by the Surgical Instruments Sectional Committee had been approved by the Medical Equipment and Hospital Planning Division Council.

This standard was first published in 1979. It has been revised to incorporate certain modifications based on the experience gained during the implementation of this standard and align it with the latest practices being followed in the field, especially in respect of the requirements of material, bend test and flexibility test. The corrosion resistance test has been modified to align it with IS 7531 : 1990 'Methods for testing of corrosion resistance of stainless steel surgical instruments ( *first revision* )'. A recommended sampling plan for suture needles has also been included.

The Indian Standard for suture needles for general surgical purposes is being issued in different parts. This part ( Part 1 ) of the standard covers the general requirements and tests applicable to all types of suture needles, thus serving as a horizontal standard for suture needles. The shapes, sizes and dimensions of suture needles are intended to be covered in subsequent parts of this standard. Part 2 of this standard covers the shapes, sizes and dimensions of eyed suture needles.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values ( *revised* )'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

# Indian Standard

## SURGICAL INSTRUMENTS — NEEDLES, SUTURE

### PART 1 SPECIFICATION

### ( First Revision )

#### 1 SCOPE

**1.1** This standard specifies the requirements for suture needles for general surgical purposes.

#### 2 REFERENCES

**2.1** The following Indian Standards are necessary adjuncts to this standard:

<i>IS No.</i>	<i>Title</i>
1501 ( Part 3 ) : 1987	Methods for Vickers hardness test for metallic materials: Part 3 Less than HV 0.2 ( <i>second revision</i> )
4905 : 1968	Methods of random sampling
7531 : 1990	Methods for testing of corrosion resistance of stainless steel surgical instruments ( <i>first revision</i> )

#### 3 MATERIAL

**3.1** The suture needles shall be made from stainless steel wire of either of the following composition:

<i>Element</i>	<i>Percentage</i>
Carbon	0.30 to 0.40
Manganese	1.00 <i>Max</i>
Phosphorus	0.045 <i>Max</i>
Sulphur	0.045 <i>Max</i>
Silicon	1.00 <i>Max</i>
Chromium	12.00 to 14.00
Nickel	1.00 <i>Max</i>
OR	
Carbon	0.60 to 0.75
Manganese	1.00 <i>Max</i>
Phosphorus	0.040 <i>Max</i>
Sulphur	0.030 <i>Max</i>
Silicon	1.00 <i>Max</i>
Chromium	16.00 to 18.00
Molybdenum	0.75 <i>Max</i>

#### 4 SIZES, SHAPES AND DIMENSIONS

**4.1** The sizes, shapes and dimensions of various types of suture needles, shall be as given in respective parts of this standard.

#### 5 HARDNESS

**5.1** Hardness of the suture needle, when tested in accordance with IS 1501 ( Part 3 ) : 1987, shall be 525 to 625 *HV*.

#### 6 WORKMANSHIP AND FINISH

**6.1** The surface of the suture needle shall be smooth and shall be free from pitting.

**6.2** The eye of the needle shall be clean and properly formed and shall be smooth from inside and outside.

**6.3** The needles shall be finished smooth and bright.

**6.4** The needles shall be free from grinding marks, polishing dirt or other material which could necessitate cleaning prior to sterilization and use.

**6.5** The point of the needle shall be sharp except where otherwise specified.

#### 7 TESTS

**7.1** The needles shall be free from feather edges, burrs and nicks, when examined under a magnification of 5X.

##### 7.2 Corrosion Resistance Test

The needles shall be tested for corrosion resistance in accordance with IS 7531 : 1990. They shall pass the test.

##### 7.3 Bend Test ( for Straight Needles )

Clamp the needle at the flat portion in a needle holder using a piece of soft leather for protection. Press the thumb against the needle

and bend it to an angle of 90°. The needle shall deem to have failed as being too hard, if it breaks before the initial bend of 90° is achieved.

#### 7.4 Flexibility Test ( for Curved Needles )

Hold the needle between the thumb and the forefinger and exert pressure inwards, so that the chordal distance between the eye and the point is reduced to 90 percent of the original value in case of 3/8 circle needles and 80 percent in case of 1/2 circle or 5/8 circle needles. Repeat the test four times. There shall not be any permanent set in the needle after the test.

#### 7.5 Sharpness Test ( for All Needles, Except Blunt Point Needle )

Push the pointed sharp end of the suture needle preperpendicularly inside the stretched aluminium foil of 0.025 mm thickness. Measure the

piercing resistance in grams. The piercing resistance shall be less than 25 g.

### 8 MARKING AND PACKING

**8.1** The packages containing the required number of needles shall be marked with the indication of the source of manufacture, shape, size, type of the eye and the quantity of suture needles.

**8.2** The suture needles shall be packed as agreed to between the manufacturer and the purchaser.

### 9 SAMPLING

**9.1** The scale of sampling and criteria for conformity of the suture needles to the requirements of this specification shall be as agreed to between the purchaser and the supplier. A recommended sampling plan is given in Annex A.

## ANNEX A

### ( Clause 9.1 )

#### SAMPLING PLAN FOR SUTURE NEEDLES

##### A-1 LOT

**A-1.1** In any consignment, all the suture needles of the same size, shape and dimensions and produced from the same material under similar conditions of manufacture shall be grouped together to constitute a lot.

**A-1.2** For ascertaining the conformity of the material to the requirements of the relevant specification, samples shall be tested from each lot separately.

**A-1.3** The number of cartons to be selected from each lot shall depend upon the size of the lot and shall be in accordance with columns 1 and 2 of Table 1.

**A-1.4** The cartons shall be selected at random from the lot. For this purpose, reference may be made to IS 4905 : 1968.

##### A-2 NUMBER OF TESTS AND CRITERIA FOR CONFORMITY

**A-2.1** From each of the cartons selected as per column 2 of Table 1, a suitable number of packets ( as per column 3 of Table 1 ) shall be selected at random. Each needle from these packets shall be inspected for sizes, shapes and dimensions, workmanship and finish. A needle failing to meet one or more of these requirements shall be considered as defective. A lot

shall be considered as having satisfied these requirements, if there is no defective in the sample.

**A-2.2** The lot having satisfied the requirements as given in A-2.1 shall be further tested for surface defects ( 7.1 ), hardness ( 5.1 ), corrosion resistance ( 7.2 ), bend ( 7.3 ), flexibility ( 7.4 ) and sharpness ( 7.5 ) as per the specification. For this purpose, a sub sample as given in column 4 of Table 1 shall be selected. Each of the needles in the sub-sample shall be subjected to these tests. A lot shall be considered as having satisfied the requirements of the specification, if there is no failure.

**Table 1 Scale of Sampling**  
( Clauses A-1.3, A-2.1 and A-2.2 )

No. of Cartons in a Lot	No. of Cartons to be Selected	No. of Packets to be Selected	
		Sample Size	Sub- sample Size
(1)	(2)	(3)	(4)
2 to 8	2	8	5
9 to 15	3	13	5
16 to 25	5	20	8
26 to 50	8	32	13
51 to 100	13	50	13
101 to 150	20	50	13
151 and above	32	80	20

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Doc : No. MHD 1 ( 2307 )

#### Amendments Issued Since Publication

Amend No.	Date of Issue	Text Affected

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